REMARKS/ARGUMENTS

Claims 1, 2, 5, 6, 14, 19, 20, 22, 26, 29, 35, and 40 have been amended by way of the present amendment. Claims 4, 16, 21, 38, and 39 have been cancelled by way of the present amendment. Thirty-four claims remain pending in the application: Claims 1-3, 5-8, 10-15, 19, 20, 22-37, and 40-42. Reconsideration of Claims 1-3, 5-8, 10-15, 19, 20, 22-37, and 40-42 in view of the amendments above arguments below is respectfully requested.

By way of this amendment, Applicants have made a diligent effort to place the claims in condition for allowance. However, should there remain any outstanding issues that require adverse action, it is respectfully requested that Examiner telephone the undersigned at (805) 781-2824 so that such issues may be resolved as expeditiously as possible.

Applicable law with regard to rejections according to 35 U.S.C § 103(a)

To establish a prima facie case of obviousness there must be some suggestion or motivation in the prior art to make the claimed invention, there must be a reasonable expectation of success, and **the prior art references must teach or suggest all of the claim limitations.** MPEP 2142; *In re Vaeck*, 947 F.2d 488, 20 USPQd, 1483 (Fed. Cir. 1991). Both the suggestion and the expectation of success must be founded in the prior art, and not in the Applicant's disclosure. *In re Dow Chemical Co.*, 5 USPQ2d 1529 (Fed. Cir. 1988). **The mere fact that the prior art can be modified does not make the modification obvious unless the prior art taught or suggested the desirablility of the modification.** *In re Gordon*, 221 USPQ1125 (Fed. Cir. 1984). **The patent office has the burden**

of establishing a prima facie case of obviousness. MPEP 2142; *In re Vaeck*, 947 F.2d 488, 20 USPQ2d, 1438 (Fed. Cir. 1991).

Turning to the specific objections and rejections:

1. Claims 1, 2, 4-6, 16, 19-22, 26, 29, 35, 37-38, 40, and 42 stand rejected under 35 USC 112, first paragraph for failing to comply with the written description requirement. Specifically, the Examiner has rejected Claims 1, 4, 5, 16, 19, 21, 22, 26, 35, 37, 40, and 42 for reciting the phrase "per pulse". Further, the Examiner has rejected Claims 2, 6, 20, 22, 26, 29, 35, 38, and 40 for reciting the negative limitation "wherein said [method] does not include the addition of a quenching agent, photoradiation sensitizer, or albumin".

Claims 1, 5, 19, 22, 26, 35, 37, 40, and 42 have been amended to cancel the language "per pulse" and replaced the phrase with "per flash". Support for the phrase "per flash" may be found in the application as originally filed at least Example 1, Example 7, and Figure 1. Claim 4 has been cancelled herewith and therefore its rejection is now moot.

Claims 2, 6, and 20 have been amended to strike the negative limitation "does not include the addition of a quenching agent, photoradiation sensitizer, or albumin". Claim 38 has been cancelled herewith and therefore its rejection is now moot. Claims 26, 29, 35, and 40 have been amended to replace the negative limitation "does not include the addition of a quenching agent, photoradiation sensitizer, or albumin" with the language "wherein said method does not include the addition of genotoxic chemical agents" as supported by the specification at page 4, lines 13-15. **The specification states that the method of inactivating microbes in the present application does NOT add possibly genotoxic chemical agents.**

2. Claims 1-8, 10-13, and 22-34 are rejected under 35 USC 103(a) as being unpatentable over O'Dwyer et al. (USPN 6,312,931) in view of Horowitz et al. (USPN 5,981,163). Claim 4 has been cancelled herewith and therefore its rejection is now moot. Claims 1-3, 5-8, 10-13, and 22-34 are not rendered obvious by the teachings of O'Dwyer et al. and Horowitz et al.

Independent claims 1, 5, and 8 have been amended to claim "a fluence per flash in the range of about 0.1 to about 0.25 J/cm^2" (see, for example, Example 11, Table 1) while O'Dwyer teaches, as stated by the Examiner in the Office Action of May 19, 2004, "a fluence greater than about 0.001 J/cm^2 to 50 J/cm^2" (col. 4, lines 41-44).

The range of 0.1 to about 0.25 J/cm2 was determined by the inventors to be useful for inactivating microbes in a biological composition, e.g. a platelet composition, while avoiding extensive protein damage or inactivation of platelets (see USSN 10/067,731 page 5, lines 3-6). Advantageously, the lower fluence range was one of the reasons that the Broad-Spectrum Pulsed Light (BSPL) treatment worked without the addition of stabilizers or other chemicals as taught by O'Dwyer et al. who adds albumin and Horowitz et al. who adds quenching agents.

The Examiner further points to column 6, lines 58-59 of Horowitz suggesting that Horowitz teaches a fluence of 0.2 J/cm^2. However, Horowitz teaches 0.2J/cm^2 as a range for UVC. Importantly, UVC fluence levels do not correspond to the BSPL treatment as taught and claimed in the present application ***because UVC is only one component of BSPL.*** Therefore, a fluence level of 0.2J/cm2 for UVC as taught by Horowitz is outside of the range of UVC light utilized in the present application. **The present application pertains to a Broad Spectrum of Pulsed Light and not Ultraviolet C light as taught by Horowitz.**

Independent claims 22, 26, and 29 have been amended to include the negative limitation "wherein said method does not include the addition of genotoxic chemical agents" as supported by the specification at page 4, lines 13-15. As argued in Applicants amendment of January 14, 2004, Horowitz and O'Dwyer teach and claim additional steps including the addition of a quenching agent and albumin, respectively. Neither of these agents are claimed in the present application. On the contrary, the present application advantageously works without the addition of potentially genotoxic chemical agents, such as a quenching agent as defined by Horowitz, and stabilizers. **As such, the teachings of Horowitz and O'Dwyer in combination DO NOT teach the claimed invention. In fact Horowitz teaches AWAY from the claimed invention.**

Assuming that the prior art references teach each of the claim limitations (which they do not), the patent office still has the burden of establishing a prima facie case of obviousness. MPEP 2142; *In re Vaeck*, 947 F.2d 488, 20 USPQ2d, 1438 (Fed. Cir. 1991). In establishing a prima facie case of obviousness, there must be some suggestion or motivation in the prior art to make the claimed invention. Furthermore, both the suggestion and the expectation of success must be founded in the prior art. However, the Examiner has not pointed out where the "suggestion or motivation" in the cited references lies to combine the two references.

Therefore, the Examiner has not established a prima facie case of obviousness and Applicants respectfully request reconsideration and withdrawal of the present rejection. Independent claims 1, 5, and 8 are distinguished from the cited references by at least the recitation of "a fluence per flash in the range of about 0.1 to about 0.25 J/cm^2." Claims 1, 5, and 8 are further distinguished from the cited references by providing a method of inactivating microbes

without the addition of stabilizers or other chemicals and with lower fluence levels (as compared to O'Dwyer and Horowitz). As claims 2 and 3 depend from claim 1, claims 6 and 7 depend from claim 5, and claims 10-13 depend from claim 8, Applicants request that the present rejection be withdrawn from claims 2, 3, 6, 7, and 10-13 as well. Independent claims 22, 26, and 29 are distinguished from the cited references by at least the recitation of "wherein said method does not include the addition of genotoxic chemical agents". As claims 23-25 depend from claim 22, claims 27 and 28 from 26, and 31-34 from 29, Applicants request that the present rejection be withdrawn from all claims 23-25, 27. 28, and 31-34 as well.

3. Claims 14-16, 19-21, 35-37, and 40-42 are rejected under 35 USC 103(a) as being unpatentable over O'Dywer et al. (USPN 6,312,931) in view of Horowitz et al (USPN 5,981,163) and further in view of Platz et al. (USPN 6,187,572). Claims 14-16, 19-21, 35-37, and 40-42 are not rendered obvious by the teachings of O'Dwyer et al., Horowitz et al., and Platz et al.

Turning to independent claims 14 and 35, the Examiner states in the Office Action of May 19, 2004 that "O'Dwyer teaches [increasing] shelf life of blood components by illuminating them with BSPL". However, Applicants have reviewed O'Dwyer and found **no reference of "shelf-life" or "increased shelf-life".** Therefore, Applicants invite the Examiner to specifically point out where in O'Dwyer "increased shelf-life" is taught. Assuming the Examiner cannot specifically point out where in O'Dwyer increased shelf life is taught, Applicants maintain that each and every element of claims 14 and 35 are not taught by the cited art. As such, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 14 and 35. As claim 15 depends from claim 14, and claims 36 and 37 from claim 35, Applicants

request that the rejection be withdrawn from all of claims 14, 15, and 35-37.

Turning now to independent claims 19 and 40, the Examiner relies, as stated in the Office Action of May 19, 2004, on Platz et al. for teaching "repeating illumination of the platelet composition every 6 hours." However, Platz doesn't apply for several reasons:

a. **Platz experiments utilize red blood cells and not platelets.** Therefore, the methods and data taught in Platz are not obviously applicable to platelets. For example, damage mechanisms may not be similar and spectral response for red blood cells is different than platelets. As will be appreciated by one of ordinary skill in the art, platelets are fragile and require different processing than red blood cells.

b. The two-minute stop cycle taught in Platz was part of an experimental protocol to determine red blood cell damage as a function of time. In the Platz experimental protocol, at the two-minute mark the suspension was mixed and sample of red blood cells were removed and diluted into 1 ml of water. **Thus, the teaching of Platz pertains to methodology for testing a red blood cell suspension and not a protocol for illumination.**

Therefore, the Platz protocol is for a different process than that described and claimed in the present application. Platz is concerned with damage to red blood cells rather than maintaining a bacteriostatic condition in a platelet composition. Thus, the Examiner has not established a prima facie case of obviousness and Applicants respectfully request reconsideration and withdrawal of the present rejection from claims 19 and 40. As claim 20 depends from claim 19 and

claims 41 and 42 from 40, it is requested that the rejection be withdrawn from all of claims 19, 20, and 40-42.

4. Claims 38-39 are rejected under 35 USC 102(e) as being anticipated by O'Dwyer et al. (USPN 6,312,931). Claims 38 and 39 have been cancelled herewith therefore their rejection is now moot.

In view of the above, Applicants submit that 1-3, 5-8, 10-15, 19, 20, 22-37, and 40-42 are now in condition for allowance, and prompt and favorable action is earnestly solicited.

Respectfully submitted,

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